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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,033	04/30/2001	Edward Rebar	019496-005820US	4301

20350 7590 04/20/2005

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EXAMINER
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SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/846,033

Applicant(s)

REBAR ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 68-71, 77 and 96-103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68-71, 77 and 96-103 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This Office Action is in response to Applicant's remarks and arguments filed on 11/15/2004. Claims 67, 75 and 95 have been cancelled. Claims 68, 96 and 100 have been amended. Claims 68-71, 77 and 96-103 are pending.
2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 103, withdrawn***

3. The rejection of claims 67, 71 and 77 under 35 U.S.C. 103(a) as being unpatentable over Pal et al. (1998) in view of Barbas, III et al. (U.S. Patent No: 6,140,466) is withdrawn in view of Applicants persuasive arguments and amendments.
4. The rejection of claims 75, 95, 99 and 103 under 35 U.S.C. 103(a) as being unpatentable over Pal et al. (1998) in view of Barbas, III et al. (U.S. Patent No: 6,140,466) and Baird (U.S. Patent No: 6,479,654) is withdrawn in view of Applicants persuasive arguments and amendments.

#### ***Claim Rejections - 35 USC § 112***

5. Claims 68-71, 77 and 96-103 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for specific zinc finger proteins to regulate the gene encoding specific VEGF, does not reasonably provide enablement for the scope of all possible zinc finger polypeptide sequences contemplated by the Applicant to regulate all the VEGF genes. Specifically, Applicants are enabled for zinc finger proteins (ZFP) recited in tables 3 and 4 to bind the human VEGF. Table 2 recites the location of the target sites. In addition, table 7 lists the zinc finger proteins that bind rat VEGF gene.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claims 68-71, 77 and 96-103 recite "modulating angiogenesis or treating a wound or treating ischemia comprising introducing a zinc finger protein into an animal having a genome comprising a target site within a vascular endothelial growth factor (VEGF) gene, whereby the zinc finger protein binds to the target site and thereby modulates angiogenesis or treating a wound or treating ischemia in the animal". However, the specification only describes, those zinc finger proteins described in table 2, 3, 4 and 7 as capable of binding VEGF gene. It is unclear if all ZFP's will bind to the various VEGF's such as VEGF-A, VEGF-B, VEGF-C and VEGF-D. Since the modulation of VEGF-A gene is required, for example to treat angiogenesis, it is

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imperative that the appropriate ZFP proteins are used to modulate VEGF-A gene. In addition, published art also indicates that zinc-finger DNA-binding domains provides for the achieving of single –gene specificity in regulating the gene. (Tan et al.). Thus, the instant specification is only enabling to those zinc finger proteins described in table 2, 3, 4 and 7 as capable of binding VEGF gene and not commensurate with all possible ZFS's modulating the various VEGF genes claimed by the Applicant. Therefore in the instant application, the lack of working examples and the quantity of experimentation needed to determine the limitless number of possible ZFPs peptide sequences modulating VEGF genes is practically infinite and the guidance provided in the specification is very limited (For example, the various tables do not teach the ZFPs the interact with the specific VEGF genes in the various species). Absent further guidance from the specification it would constitute undue experimentation to determine all the claimed polypeptides contemplated by the Applicants in regulating VEGF. As such, claims 68-71, 77 and 96-103 are not commensurate in scope with the specification but rather is broader than the supporting disclosure.

6. No claims are allowable.

### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 04/05

  
JANET ANDRES  
PRIMARY EXAMINER